



State of Utah

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DIVISION OF WATER QUALITY
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MEMORANDUM

TO: Water Quality Board

THROUGH: Walter Baker

FROM: Erica Gaddis

DATE: November 30, 2015

SUBJECT: Independent Scientific Review

Independent peer review is an integral part of the scientific process. Legislation has recently been drafted that would require independent peer review of virtually all future water quality actions and initiatives (Attachment 1). The purpose of this memorandum is to provide the Water Quality Board with context to this proposed legislation and to initiate dialogue about several important aspects that need to be considered if formal peer review requirements are to be initiated. To illustrate these considerations the Division has drafted administrative rules (Attachment 2) for independent scientific review with alternative language that addresses several concerns with the current legislative proposal. We are not asking the Water Quality Board for authorization to initiate rule-making as we continue to refine our rule language and intent. Instead, we are sharing the draft rule language, as well as the draft legislation, with the Water Quality Board as an informational item because it could significantly affect the processes that govern the work of the Board.

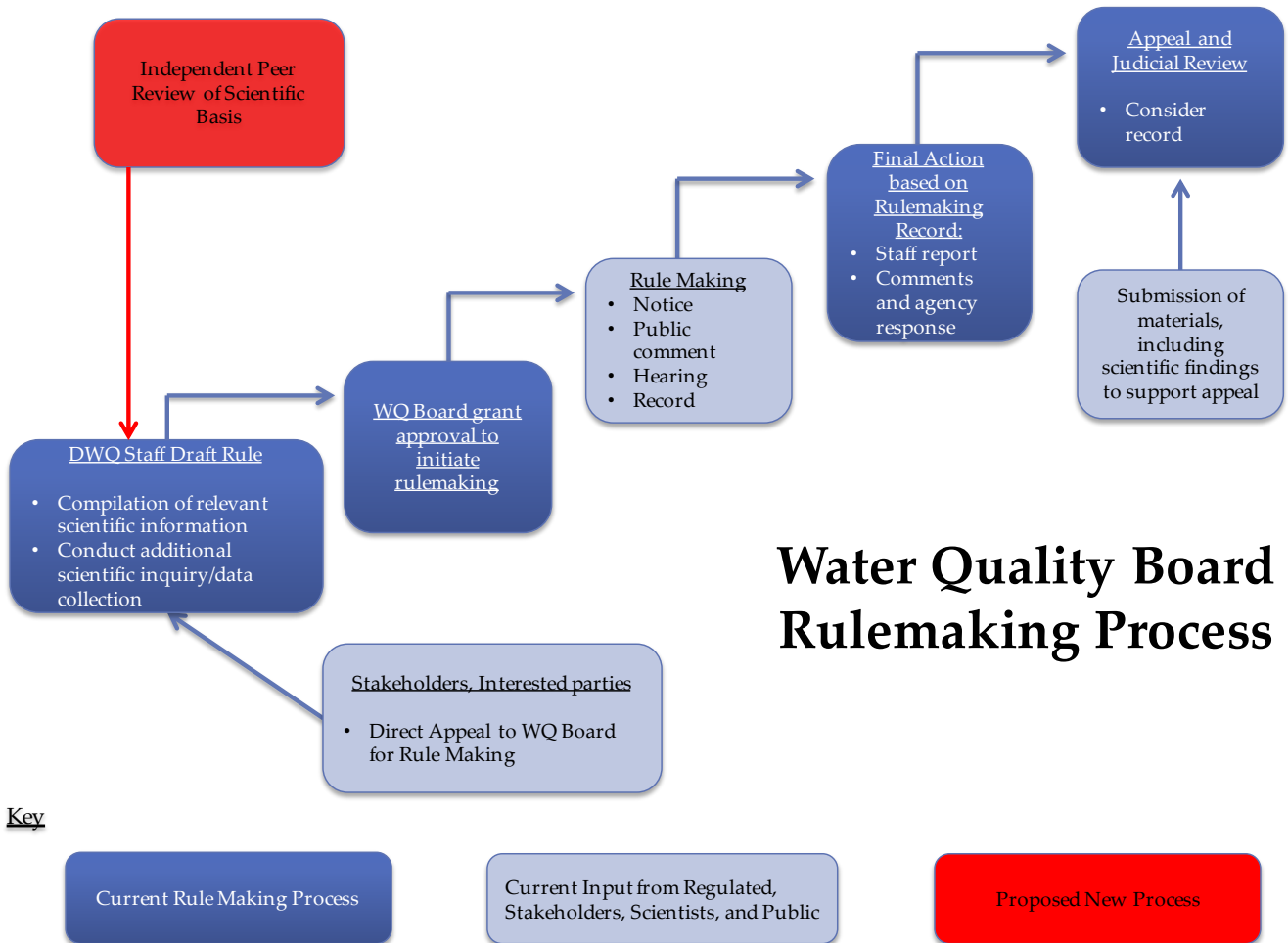
Background

Publicly Owned Treatment Works (POTWs) that discharge wastewater to the Jordan River, Great Salt Lake, and Utah Lake are proposing a statutory change that would allow permittees to challenge the science behind Division of Water Quality (DWQ) studies, proposed rules, permits, TMDLs, and other initiatives through a peer-review process. DWQ supports an independent scientific review process and believes it can be an important aspect of good governance. DWQ sees merit in independent scientific reviews and has always welcomed outside review via numerous technical workgroups and public comment on any new water quality proposals. There is potential merit in formalizing these current practices. However, we see several shortcomings with the legislative approach the POTWs have proposed. In this white paper, DWQ outlines how an independent scientific review process could fit into the current administrative rule-making process, elements of peer review that should be considered to better meet the intent of the proposed legislation without running afoul of existing water quality processes, and potential ways

to strengthen the existing legislative proposal to address the concerns of DWQ staff and the office of Utah’s Attorney General. To provide additional context we also provide background into the successes and failures of similar proposals that have been implemented in other states.

Incorporating Independent Scientific Review into the Current Administrative Process

The Division is governed by both the state Utah Water Quality Act (Title 19, Chapter 5) and the federal Clean Water Act (CWA), both of which include administrative procedures designed for public comment, judicial and executive review, and regulatory transparency. The Division suggests that a new scientific review process not interfere or constrain the existing process as outlined in the following diagram.



Water Quality Board Rulemaking Process

The Utah Water Quality Board (WQB) is a citizen board whose members are appointed by the governor and confirmed by the legislature. All DWQ administrative rules must be approved by the WQB following the process described in UCA §63G-3. The WQB is statutorily responsible for:

- Developing programs for the control of pollution to Utah’s waters (UCA §19-5-104(3)(a))
- Making rules governing wastewater treatment works (UCA §19-5-104(2))
- Adopting water quality standards (UCA §19-5-104(3)(b))

Any new independent scientific review requirements should complement rather than contradict the following existing opportunities for stakeholders to provide scientific input to the rule-making process:

- DWQ convenes technical advisory committees to ensure that proposed rules are scientifically defensible. Examples include: nutrient technical committee, Jordan River technical committee, Rockport and Echo Reservoir TMDL technical committee. Permittees are always invited to serve on these committees.
- DWQ relies on workgroups composed of diverse stakeholder interests to inform policy making. Examples include: Nutrient Core Team, Water Quality Standards Workgroup, and Water Quality and Health Advisory Panel.
- Any person may propose a rule to the WQB for consideration (UCA §63G-3-601(2))
- During the rule making process, DWQ solicits and responds to comments (UCA §63G-3-301).
- Following rulemaking, any person aggrieved by a rule may obtain judicial review by filing a complaint in District Court (UCA §63G-3-602). Individuals may also petition the Water Quality Board to initiate rulemaking.
- The Utah Legislature’s Administrative Rules Review Committee oversees rule making and rule impact.

Benchmarking with Other States

DWQ conducted a survey through the national Association of Clean Water Administrators regarding peer-review processes in other states. The overwhelming majority of states do not have a mandated peer-review process. Three states have mandated peer-review processes, summarized in Table 1 below.

Table 1. Summary of peer review process in other states

	Mandated in Statute/Rule	Year	Detailed process	Binds agency decisions	Applicability	Process
Minnesota	Statue: Section 100. [115.035]	2015	TBD	No	Any water quality standard at discretion of commissioner.	TBD
California	Statue: Section 57004	1997	Guidance document	No	Any rule passed by CalEPA boards	Administered by the Office of Peer Review with a contract with University of California
New Jersey	Rule: Admin Order No. 2009-05	2009	Guidance documents	No	Any issue facing NJDEP at discretion of commissioner.	Administered by Office of Science through a standing Science Advisory Board appointed by Commissioner

Although the processes are generally positive, we received the following comments from agency staff in California and Minnesota.

“The peer review process can be very inefficient. One person identifies and assigns potential reviewers for the entire State. This is a lengthy process that considers the expertise of the possible reviewers and includes measures to avoid conflicts of interest. Then those engaged in the rule-making work directly with the reviewers. Reviewers may or may not be available when the State needs them. They are often professors and their schedules and priorities do not necessarily align with ours. Their understanding of their role varies too. Nevertheless, sometimes the process works quite well, and invariably, it helps to be able to tell stakeholders and decision-makers that

proposed rules have been subjected to scientific peer review. (Note that we are not required to make changes based on these reviews, but we must respond in writing for the record and may make changes if we agree.)” – *Bill Johnson, California State Water Board*

“MPCA has typically relied on the scientific peer-reviewed literature for the scientific underpinning for standards development. Sometimes we [MPCA] get questions/challenges that are framed as scientific concerns, but are really more policy concerns. In that case I don’t think that convening a panel of scientists to conduct a peer review is all that useful, since we aren’t faced with a science question, it’s a policy question. Sometimes there are multiple approaches we could take and we need to show that the approach we took was needed and reasonable. Science can help us understand the implications of policy decisions and various approaches, but it doesn’t tell us which policy choice to make. Scientific peer review of a policy question could be time-consuming and costly, and not all that helpful if it isn’t really a scientific question. We also hear concerns that are more about implementation than about the standard. I used mercury as an example of a very low standard that is based on what level of mercury is too much for human health. The standard is what we need to achieve, but we can’t always get there right now due to technology limits. Those are two different questions, and doesn’t mean that the standard is wrong.” – *Shannon Lotthammer, Minnesota Pollution Control Agency*

Elements of a Good Independent Scientific Review Process

Scientific review is integral to sound science. Traditionally peer review involves the selection of independent scientific experts, who are asked to review and critique the methods, results and findings of scientific research. Typically reviewers focus on the extent to which findings are novel, follow accepted scientific practices, and are of interest to other scientists. The peer review process is integral to scientific inquiry as the best available quality assurance procedure available to modern science. The peer review processes can be adapted to inform the scientific basis of regulatory decisions, but if this is to occur, the requirements should explicitly address the following considerations:

- **Independent process.** There should be no real or perceived conflict-of-interest by any member of the scientific review panel. Most of the qualified scientists in Utah have partnered with DWQ and/or the regulated community on scientific projects that support DWQ initiatives. Thus, reviewers will likely need to be qualified scientists from outside of Utah. To avoid bias, the reviewers should also be mutually agreed upon by DWQ and the party requesting peer review.
- **Science-oriented not policy-oriented.** Regulatory decisions are informed by sound science, but science alone is incapable of accounting for the many important social, economic and political considerations that are integral to crafting sound policy. Technical regulatory reviews need to be limited to the scientific basis of the proposal. Technical experts should not be tasked with making determinations on policy matters.
- **Reflect the limits of science.** Science is not black and white and it is important for the review panel to reflect its limits. DWQ will always need to make decisions with uncertain and imperfect science. Scientific review could help quantify and characterize uncertainty as it relates to the scientific underpinnings of policies, however black-and-white

recommendations are unlikely because such decisions are inconsistent with the tenets of scientific inquiry.

- **Inform but not prescribe policy decisions.** The existing rule-making process (UCA §63G-3-301(3)) requires agencies to develop and use flexible approaches in drafting rules. Such flexibility should be preserved and policy decisions should not be delegated from the agency or governing board to a group of scientists that are most likely non-Utahns. No other state or federal agency binds policy recommendations or decisions by comments obtained through scientific review processes.
- **Independent scientific review should be open to all stakeholders.** If the independent scientific review concept is sound, DWQ believes that it should be made available to all stakeholders who are potentially affected by proposed water quality actions. No other state limits the process of scientific review or challenges solely to the regulated community.
- **Established in Rule rather than in Statute.** The Division already has statutory authority to establish a scientific review process (63G-3-301(3) and 19-5-106(g)). Establishing the details of the process in administrative rule will provide more flexibility in how to execute an independent scientific review as the initiatives of DWQ change over time. This template is followed in California and Minnesota. New Jersey's program was formed under administrative rule. No state currently defines the details of a scientific review process in statute.
- **Maintain government efficiency.** Changes to the current rule-making process must be carefully evaluated to ensure that they do not add unnecessary costs or delays in program implementation. DWQ suggests placing a limit on the amount of time available for peer review (e.g., 6 months to 1 year). California agency staff indicates that the peer-review process is very inefficient and can result in significant delays in the rule-making process. The fact that the current proposal includes changes to permits means that such delays could potentially be translated to permitting, with a corresponding potential to hamper economic development.

Comparison of POTW and DWQ Proposed Peer-review

There are some very important differences related to scope and process between the legislation proposed by the POTW group and the administrative rules that have been drafted by Division staff. These differences are summarized in a table provided as Attachment 3 to this memorandum.

References

To explore these issues and concerns further, we highly recommend the following reports related to integration of scientific review with policy making.

OECD (2015), "Scientific Advice for Policy Making: The Role and Responsibility of Expert Bodies and Individual Scientists", OECD Science, Technology and Industry Policy Papers, No. 21, OECD Publishing, Paris. Available at <http://dx.doi.org/10.1787/5js3311jcpwb-en>

Salzman, J. and J.B. Ruhl, In Defense of Regulatory Peer Review, 84 *Washington University Law Quarterly* 1-48 (2006). Available at: http://scholarship.law.duke.edu/faculty_scholarship/1599

USEPA. Peer Review Handbook: 4th Edition. Available at:
http://www2.epa.gov/sites/production/files/2015-09/documents/final_epa_peer_review_handbook-4th_ed_091415_dummy_link.pdf

Attachment 1. Legislation Proposed by POTW Community

WATER QUALITY AMENDMENTS

Section 1

19-5-105.3 Independent Peer Review of Water Quality Studies and Standards.

(1) For the purposes of this chapter:

- (a) “Independent peer review” means a technical or scientific peer review conducted by experts having technical expertise in the the work being reviewed who are not;
 - i. Currently conducting research funded by the Utah Division of Water Quality (UDWQ) or the Challenging Party;
 - ii. Employed by an entity that is regulated under the Utah Water Quality Act;
 - iii. A spouse or close family member of someone who is employed by UDWQ or the Challenging Party;
 - iv. An active, participatory member of a non-profit organization that advocates positions or otherwise lobbies on UDEQ issues or proposals.
- (b) “Challenging Party” means a permittee regulated under the Utah Water Quality Control Act
- (c) “Proposal” means an initiative to change water quality standards, impose TMDL’s, modify permits, or other regulatory guidance, including reinterpretations of water quality standards or other changes that will financially impact citizens or businesses within the State of Utah; and,
- (d) “Study” means a study, analysis, or other technical or scientific work that was conducted, contracted, available, or otherwise relied upon by the Division and that is or will be used to support or otherwise inform a regulatory or permitting decision-making process.
- (e) “Technology based effluent limits” are numeric limitations included in a permit based on the availability of technology to reach the permit limit rather than on a water quality standard or TMDL.

(2) The Director shall ensure that any study or proposal prepared by or under the direction of the Division or used to support permits or proposed rules, including technology based effluent limits, considered by the Board in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act is subject to an independent peer review when the following conditions are met;

- (a) A Challenging Party challenges the technical or scientific basis upon which the proposal, study, technology based effluent limits, permit condition, or proposed rule is based; and
 - (b) The Challenging Party agrees to and provides the funding necessary to pay for the peer review process.
 - (c) The peer review process is completed within one year from the date the peer review panel is selected such that it does not result in inordinate delays with respect to the permitting or regulatory process.
- (3) If there are more than one Challenging Party challenging the technical or scientific basis of the same proposal, their specific challenges will be consolidated for the peer review process. Those challenging and requesting the peer review will be responsible for the costs of the peer review and the allocation of the costs to the challenging parties. They will also have the responsibility of selecting a sole independent expert to represent the challenging entities in accordance with 19-5-105.3(4).
- (4) When a peer review is conducted, there shall be three independent experts appointed by the director to the peer review panel that are mutually agreeable to both UDWQ and the Challenging Party. In the event that the Peer Review Panel is not appointed within thirty to sixty (30-60) days from the time that the Director receives the request for a Peer Review panel, the following default provision for Peer Review Panel selection will be activated:
- (a) One independent expert selected by the Division;
 - (b) One independent expert selected by the point or non-point source entity(ies) challenging the proposal or study; and
 - (c) One independent expert mutually agreeable to the independent experts identified above in (a) & (b).
- (5) The peer review panel shall ensure that a proposal, study or proposed rule, including a technology based effluent limit, subject to an independent peer review under this section is reviewed in general accordance with the guidance contained in the United States Environmental Protection Agency's Peer Review Handbook. As part of the independent peer review process, the Peer Review Panel shall allow for public comment, including written and oral public comments, on the proposal, study, permit condition, or proposed rule.
- (6) Findings of the Peer Review Panel shall be incorporated into the proposal, study, permit, TMDL or proposed rule as needed to ensure the scientific accuracy of the proposal and shall become a part of the record related to the proposed study, TMDL or rule.
- (7) The Peer Review Panel shall conclude with written findings supported by at least two of members of the Panel finding one of the following:

- (a) The proposal reviewed is not scientifically defensible;
- (b) The proposal reviewed is scientifically defensible; or,
- (c) The proposal reviewed is scientifically defensible with conditions developed by the Peer Review Panel.

(8) If the Peer Review Panel is examining a technology based effluent limit for a specified downstream water body or series of hydrologically connected water bodies, the Peer Review Panel shall conclude with written findings supported by at least two of the Peer Review Panel members finding one of the following:

- (a) The technology based effluent limit is not scientifically necessary to protect the designated beneficial uses of specified downstream water body or series of hydrologically connected water bodies; or,
- (b) The technology based effluent limit is scientifically necessary to protect the designated beneficial uses of a specified downstream water body or series of hydrologically connected water bodies.

(9)(a) Those proposals reviewed and found scientifically defensible or scientifically defensible with conditions may be forwarded to the Water Quality Board for further consideration.

(b) Challenging Party(ies) with technology based effluent limits that are not scientifically necessary to protect identified downstream water bodies are exempt from compliance with technology based effluent limitation evaluated.

**Attachment 2. Example of Administrative Rules for Independent Scientific Review drafted
by Division of Water Quality**

R317. Environmental Quality, Water Quality.

R317-1. Definitions and General Requirements.

R317-1-1. Definitions.

"Assimilative Capacity" means the difference between the numeric criteria and the concentration in the waterbody of interest where the concentration is less than the criterion.

"Biological assessment" means an evaluation of the biological condition of a water body using biological surveys and other direct measurements of composition or condition of the resident living organisms.

"Biological criteria" means numeric values or narrative descriptions that are established to protect the biological condition of the aquatic life inhabiting waters that have been given a certain designated aquatic life use.

"Board" means the Utah Water Quality Board.

"BOD" means 5-day, 20 degrees C. biochemical oxygen demand.

"Body Politic" means the State or its agencies or any political subdivision of the State to include a county, city, town, improvement district, taxing district or any other governmental subdivision or public corporation of the State.

"Building sewer" means the pipe which carries wastewater from the building drain to a public sewer, a wastewater disposal system or other point of disposal. It is synonymous with "house sewer".

"CBOD" means 5-day, 20 degrees C., carbonaceous biochemical oxygen demand.

"COD" means chemical oxygen demand.

"Conflict of interest" means any financial or other interest which conflicts with the service of an expert because it: 1) could impair the individual's objectivity or 2) could create an unfair competitive advantage for any person or organization.

"Deep well" means a drinking water supply source which complies with all the applicable provisions of the State of Utah Public Drinking Water rules.

"Digested sludge" means sludge in which the volatile solids content has been reduced to about 50% by a suitable biological treatment process.

"Director" means the Director of the Division of Water Quality.

"Division" means the Utah State Division of Water Quality.

"Domestic wastewater" means a combination of the liquid or water-carried wastes from residences, business buildings, institutions, and other establishments with installed plumbing facilities, together with those from industrial establishments, and with such ground water, surface water, and storm water as may be present. It is synonymous with the term "sewage".

"Effluent" means the liquid discharge from any unit of a wastewater treatment works, including a septic tank.

"Existing Uses" means those uses actually attained in a water body on or after November 28, 1975, whether or not they are included in the water quality standards.

"Expert" means a person with technical expertise, knowledge, and/or skills in a subject matter of relevance to a specific water quality investigation including persons from other regulatory agencies, academia, or the private sector.

"Highly Influential Scientific Assessment (HISA)" is a

scientific assessment (i.e., an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions and/or applies best professional judgment to bridge uncertainties in the available information) that the Director reasonably can determine could have a potentially significant financial impact on either the public or private sector or is novel, controversial, or precedent-setting.

"Human-induced stressor" means perturbations directly or indirectly caused by humans that alter the components, patterns, and/or processes of an ecosystem.

"Human pathogens" means specific causative agents of disease in humans such as bacteria or viruses.

"Independent Scientific Review" means a technical or scientific review conducted by expert(s) in an area related to the material being reviewed who were not directly or indirectly involved with the development of the material to be reviewed and who does not have a real or perceived conflict of interest.

"Industrial wastes" means the liquid wastes from industrial processes as distinct from wastes derived principally from dwellings, business buildings, institutions and the like. It is synonymous with the term "industrial wastewater".

"Influent" means the total wastewater flow entering a wastewater treatment works.

"Influential Scientific Information (ISI)" means scientific information that the Director reasonably can determine will have or does have a clear and substantial impact on rule making or regulatory decisions. ISI may include information submitted by external organizations. Examples of ISI include work that establishes a significant precedent, model, or methodology; addresses significant controversial issues; focuses on significant emerging issues; or considers an innovative approach for a previously defined problem, process or methodology.

"Great Salt Lake impounded wetland" means wetland ponds which have been formed by dikes or berms to control and retain the flow of freshwater sources in the immediate proximity of Great Salt Lake.

"Large underground wastewater disposal system" means the same type of device as an onsite wastewater system except that it is designed to handle more than 5,000 gallons per day of domestic wastewater, or wastewater that originates in multiple dwellings, commercial establishments, recreational facilities, schools, or any other underground wastewater disposal system not covered under the definition of an onsite wastewater system. The Division controls the installation of such systems.

"Onsite wastewater system" means an underground wastewater disposal system for domestic wastewater which is designed for a capacity of 5,000 gallons per day or less and is not designed to serve multiple dwelling units which are owned by separate owners except condominiums and twin homes. It usually consists of a building sewer, a septic tank and an absorption system.

"Operating Permit" is a State issued permit issued to any wastewater treatment works covered under Rules R317-3 or R317-5 with the following exceptions:

A. Any wastewater treatment permitted under Ground Water Quality Protection R317-6.

B. Any wastewater treatment permitted under Underground Injection Control (UIC) Program R317-7.

C. Any wastewater treatment permitted under Utah Pollutant Discharge Elimination System (UPDES) R317-8.

D. Any wastewater treatment permitted under Approvals and Permits for a Water Reuse Project R317-13.

E. Any wastewater treatment permitted by a Local Health Department under Onsite Wastewater Systems R317-4.

"Person" means any individual, corporation, partnership, association, company, or body politic, including any agency or instrumentality of the United States government (Section 19-1-103).

"Point source" means any discernible, confined and discrete conveyance including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, concentrated animal feeding operation, or vessel or other floating craft from which pollutants are or may be discharged. This term does not include return flow from irrigated agriculture.

"Pollution" means such contamination, or other alteration of the physical, chemical, or biological properties of any waters of the state, or such discharge of any liquid, gaseous or solid substance into any waters of the state as will create a nuisance or render such waters harmful or detrimental or injurious to public health, safety or welfare, or to domestic, commercial, industrial, agricultural, recreational, or other legitimate beneficial uses, or to livestock, wild animals, birds, fish or other aquatic life.

"Requesting Party" is an entity regulated under the Utah Water Quality Act or a stakeholder representing a public or private interest that is requesting review the scientific basis of a proposed rule.

"Scientific basis" means the foundations of a rule, regulatory guidance, or a regulatory tool that are premised upon, or derived from, empirical data or other scientific findings, conclusions, or assumptions.

"Sewage" is synonymous with the term "domestic wastewater".

"Shallow well" means a well providing a source of drinking water which does not meet the requirements of a "deep well".

"Sludge" means the accumulation of solids which have settled from wastewater. As initially accumulated, and prior to treatment, it is known as "raw sludge".

"SS" means suspended solids.

Total Maximum Daily Load (TMDL) means the maximum amount of a particular pollutant that a waterbody can receive and still meet state water quality standards, and an allocation of that amount to the pollutant's sources.

"Treatment works" means any plant, disposal field, lagoon, dam, pumping station, incinerator, or other works used for the purpose of treating, stabilizing or holding wastes. (Section 19-5-102).

"TSS" means total suspended solids.

"Underground Wastewater Disposal System" means a system for underground disposal of domestic wastewater. It includes onsite wastewater systems and large underground wastewater disposal systems.

"Use Attainability Analysis" means a structured scientific assessment of the factors affecting the attainment of the uses specified in R317-2-6. The factors to be considered in such an analysis include the physical, chemical, biological, and economic use removal

criteria as described in 40 CFR 131.10(g) (1-6).

"Wastes" means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt, and industrial, municipal, and agricultural waste discharged into water. (Section 19-5-102).

"Wastewater" means sewage, industrial waste or other liquid substances which might cause pollution of waters of the state. Intercepted ground water which is uncontaminated by wastes is not included.

"Waters of the state" means all streams, lakes, ponds, marshes, water-courses, waterways, wells, springs, irrigation systems, drainage systems, and all other bodies or accumulations of water, surface and underground, natural or artificial, public or private, which are contained within, flow through, or border upon this state or any portion thereof, except that bodies of water confined to and retained within the limits of private property, and which do not develop into or constitute a nuisance, or a public health hazard, or a menace to fish and wildlife, shall not be considered to be "waters of the state" under this definition (Section 19-5-102).

R317-1-10. Independent Scientific Review.

10.1 Applicability

(a) Independent scientific review applies to the scientific basis used to inform rule making by the Utah Water Quality Board in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act (e.g., water quality standards, TMDLs, technology based limits), or regulatory tools or guidance. Scientific review associated with permit issuance will be governed by the Administrative Procedures Act (Title 63G-4).

(b) The Director shall ensure that an independent scientific review will be conducted for Highly Influential Scientific Assessments (HISAs). The Director may conduct an independent scientific review on influential scientific information (ISI).

(c) The Director shall facilitate an independent scientific review of other scientific information when the following conditions are met:

- i. A requesting party requests the review in writing.
 - ii. The requesting party agrees to provide the necessary funding for the independent scientific review.
 - iii. The scientific basis used to support the rule, regulatory guidance, or regulatory tool has not already been subject to an independent scientific review.

10.2 Review process

(a) An independent scientific review shall be conducted by at least three independent experts appointed to a review panel by the Director.

(b) The Director shall develop clear charge questions with input from stakeholders that define the scope of the review. The questions shall focus on the degree of certainty with respect to the

interpretation or application of the scientific basis of a proposed rule, regulatory guidance, or regulatory tool.

(c) If the independent scientific review is initiated through 10.1 (c), the panel members and the charge questions shall be mutually agreed to by both the Director and the requesting party within 90 days of the request to conduct an independent review process. If panel members or charge questions cannot be agreed upon by both parties, the Water Quality Board will make the independent expert selections and finalize the charge questions.

(d) Experts shall not have a real or perceived conflict of interest nor shall they have participated in the development of the material undergoing review.

(e) The process of managing the independent scientific review may be any of the following: directly by the Director; through the United States Environmental Protection Agency's formal peer review process; an independent contractor; or through a blind review process administered by an independent organization such as a the editorial board of a relevant scientific journal, an appropriate trade organization, or a research institute.

(f) The independent scientific review process will be conducted in general accordance with the guidance contained in the United States Environmental Protection Agency's Science and Technology Policy Council Peer Review Handbook 4th Edition.

(g) To avoid inordinate delays in rulemaking or other regulatory decisions, the independent scientific review must be completed within one year following a formal request to be considered.

10.3 Use of independent scientific review results

(a) Each expert on the review panel will submit a written report with responses to the charge questions and an evaluation of the scientific basis of the proposed rule, regulatory guidance, or regulatory tool. If the majority of the review panel experts conclude that the Director has failed to demonstrate that the proposed rule, regulatory guidance, or regulatory tool has a sound scientific basis, the report shall state that finding and the underlying rationale for making the determination and any applicable and reasonable remedies to their concerns. If expert concerns are based on scientific uncertainty, then the report should estimate the relative extent of this uncertainty and the potential for this uncertainty to impact the charge questions or proposed rule.

(b) Recommendations from the review panel will be considered by the Director in the finalization of proposed rules, regulatory guidance, or regulatory tool, or by the Water Quality Board to inform rule making.

(d) The Director will document how the findings of the experts were applied to the proposed rule, regulatory guidance or tool.

(e) The Director shall ensure that the findings of the independent scientific review process are made available during any public comment period associated with the proposed rule or regulatory guidance or tool.

(f) Findings of the independent scientific review shall become part of the administrative record.

Attachment 3. Comparison of POTW and DWQ Proposed Scientific Review Process

Issue	POTW Legislation	DWQ Draft Admin Rules	Comments
Administrative process	Establishes details in statute.	Uses existing statutory authority and provides details in administrative rule.	DWQ prefers that the scientific review process be specified in rule because statutory authority is already provided for this activity (63G-3-301(3) and 19-5-106(g)).
Scope (water quality initiatives)	<ul style="list-style-type: none"> • Water quality standards (new, changes, and reinterpretation) • TMDL development • Technology based limits • Variance requests for technology based limits • Regulatory guidance • Implementation of previously approved TMDLs and standards • Permitting (modification) • Study or technical analyses 	<ul style="list-style-type: none"> • Water quality standards (new or changes to existing) • TMDL development • Technology based limits • Variance requests for technology based limits • Regulatory guidance and tools 	<p>Changes to permits should be addressed via existing administrative appeal processes.</p> <p>The scope should not be retrospective. That is, previously adopted standards, TMDLs, etc., should not be subject to additional peer review.</p>
Limits to review scope	None, provided challenging party pays costs.	Focus on “Highly Influential Scientific Assessments (HISA)” and “Influential Scientific Information (ISI)” with inclusion of other scientific information at request of external party.	Independent reviews should be required for work products that meet a significance test. A mechanism for avoiding trivial reviews is needed to ensure that agency resources are used efficiently.
Requests for review	Limited to permittees.	<p>Any stakeholder can make a request.</p> <p>Requires DWQ to conduct independent reviews for expensive or controversial initiatives.</p>	<p>There are several rationales for allowing any affected stakeholder to challenge the scientific basis of agency rules, guidance, and tools, including:</p> <ul style="list-style-type: none"> • Fairness and equitable access to governing processes • Stakeholders, other than permittees, are impacted by agency actions including non-regulated sectors such as agriculture, recreationists, and the general public
Panelist selection	3 reviewers mutually agreed upon.	Minimum of 3 reviewers mutually agreed upon.	

Applicable Content	Does not distinguish between science and policy considerations.	Limits reviews to the scientific basis of initiatives.	DWQ actions are informed by both science and policy. The agency should not delegate its responsibility for making policy decisions to largely out-of-state scientists.
Development of review charge questions	Not included.	Developed in consultation with requesting party (if applicable) and framed to address questions of uncertainty.	Framing questions are important because they: <ul style="list-style-type: none"> • define the scope of reviews • ensure continuity among reviewers responses • increase the likelihood that reviews result in actionable material
Resolving disagreement	1 reviewer selected by permittee 1 reviewer selected by DWQ 1 reviewer mutually agreed upon	Water Quality Board resolves disputes.	There is a need for independent arbitration by a breadth of stakeholders, which is an important role for the Board.
Results of Peer Review	Requires black and white determination of scientific defensibility.	Encourages reviews that highlight the uncertainty associated with complex scientific questions in the context of specific charge questions.	Technical experts should not be limited, particularly in statute, to responses that ignore the nature of scientific inquiry. Limiting the reviews to a limited number of responses may obscure important nuances that the reviews would otherwise ignore.
Funding	Challenging party pays cost.	DWQ pay for review of all HISA documents and some ISI at discretion of Director. If review is requested by external party, the requesting party will pay cost of review.	Proactive, independent reviews of the underlying technical basis of agency decisions should be routinely conducted if the ramifications are potentially expensive or expansive in the context of regulatory policy.
Authority	Binds agency staff to findings of peer review in making policy recommendations to the WQB including items for which the board does not have statutory authority over (e.g., permits).	Informs the rule and policy-making processes but does not dictate to them.	Agency decisions should be informed by science, but also should not ignore other important considerations (e.g., state or federal rules, economic impacts).